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A EUROPEAN COMMON FRAMEWORK FOR HEALTH: A REAL POSSIBILITY OR AN IMPROBABLE MYTH? LESSONS FOR THE FUTURE HEALTHCARE SYSTEM IN THE UNITED STATES

*Federico de Montalvo**

Because we were part of a clinical trial, none of us paid for it. Then the trial was declared a success and terminated before some patients had completed their treatments. That meant families had to have insurance to cover the rest or pay for them out of pocket. Our family had the necessary resources as well as excellent insurance coverage. But other heartbroken parents pleaded with the doctors: What chance does my child have if I can only afford half of the prescribed treatments? Or two thirds? I've sold everything. I've mortgaged as much as possible. No parent should suffer that torment. Not in this country. Not in the richest country in the world.

Access to healthcare is the great unfinished business of our society.

Sen. Edward Kennedy

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I. INTRODUCTION: THE LACK OF A COMMON HEALTHCARE AREA ACROSS EUROPE AS A PARADIGM OF THE DIFFICULTIES OF CONSTRUCTING A UNITED EUROPE

If there is a paradigm of the difficulties faced in constructing a future united Europe, it is to be found within the area of the health sector, in particular, with reference to management and delivery of health services. Thus, while it appears that the objective of creating a common European space in general is a process already well under way, it has not reached health policy. Therefore it can be stated that, although there are some specific health policies in the sphere of the European Union, by contrast, there is no single common health policy¹.

In addition, this matter is especially significant for two reasons: the economic importance of the health sector; and public perception regarding health protection.

A. The economic importance of the health sector

First, from an economic standpoint, the amount of activity involving the management and delivery of health services in the European Union represents more than nine percent (9.6%) of the GDP². Year after year, this amount has increased, meaning that the future prediction could be well over half (50%). Total health care spending rose from around 5% of GDP in 1970 to over 8% in 1998, with most of this increase occurring before 1990. "Public health care spending followed the same trend, growing faster than GDP from 1970 to 1990 (rising from 3.9% of GDP to some 6%), and at a slightly lower rate since 1990 as a result of efforts to rein in public spending in all Member States."³ In addition, the rate of Growth of the Health Expenditure/GNP ratio has slowed down in the last ten years.⁴

In any case, the importance of the expenditure for this sector remains high and continues to rise⁵.

1. A key example of this lack of a genuine common healthcare policy is the absence of a European Commissioner for Health, medical matters being undertaken primarily by Directorate-General for Health and Consumers (SANCO). One can access said authority through its web site at http://ec.europa.eu/dgs/health_consumer/index_en.htm

2. European Commission, *Joint Report on Health Systems*, OCCASIONAL PAPERS 74, at 11 (Dec. 2010).

3. *Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on 'The future of health care and care for the elderly: guaranteeing accessibility, quality and financial viability'*, at 3, COM (2001) 723 final (Dec. 5, 2001).

4. Nevertheless, it does not appear that this slowdown can be attributed to the economic crisis because there has not been a significant decline in health spending even when economic growth slows. *Opinion of the European Economic and Social Committee on 'Healthcare'*, 2003 O.J. (C 234) 1, 3.

5. *Communication from the Commission to the Council*, *supra* note 4, at 3. The increasing effectiveness and efficiency of health care and long-term care and getting more money out of the resources allocated to

However, the maxim; “the greater the spending on healthcare, the better the care and the system” is not true. Both the World Health Organization (WHO) and Organisation for Economic Co-Operation and Development (OECD) have noted that “the best health status is not always found in those countries that spent the most on health.”⁶

Thus, opportunities exist for States to promote the improvement of health care quality without increasing or even reducing the current level of resources spent on health.

This growth in spending is due, essentially, to three well-known facts: (1) the aging population, (2) technological progress, and (3) the constant increase in demand from citizens⁷. Besides these, other factors, such as climate change and the impact on the health of the population can affect spending⁸.

It has also been noted that the increase in litigation against physician performance (malpractice) and the additional cost of defensive medicine causes professionals to fear being exposed to a claim. However, studies analyzing the problem do not give too much importance to this in relation to the rising cost of health services⁹.

(i) The Aging Population

The aging population is one of the most influential factors on health spending. Data on aging in the coming decades warns of a significant increase in spending. Eurostat forecasts suggest that the proportion of the population aged 65 or over will rise from 17.1% in 2008 to 30% in 2060. The average ratio between people of working age (15-64) and people aged 65 and over will change from 4:1 now to 2:1 in 2050¹⁰. Between 2008 and 2060 the population of the EU-27 aged 65 and over is projected to increase by 66.9 million and the “very old” (80+) will be the fastest growing segment of the population¹¹. In addition, in 2050, according to this data supplied by Eurostat, longevity will increase, meaning that the average age

the sector are likely to become one of the most important challenges in the coming years. See *Joint Report on Health Systems*, *supra* note 2, at 11.

6. *Joint Report on Health Systems*, *supra* note 2, at 75.

7. It has been estimated that amount may increase shortly from 0.7 and 2.2%. *Joint Report on Health Systems*, *supra* note 2, at 11. In 2005, France’s health spending exceeded ten percent (11.1%) of the nation’s GDP. *Id.* at 44.

8. *Joint Report on Health Systems*, *supra* note 2, at 13.

9. See, e.g., Gerard F. Anderson et al., *Health Spending In The United States And The Rest Of The Industrialized World*, 24 HEALTH AFFAIRS, 903, 910 (2005).

10. Opinion 2011/C44/02 of the European Economic and Social Committee on “The impact of population ageing on health and welfare systems” (exploratory opinion).

11. Green Paper of the on the European Workforce for Health, Dec. 10, 2008, at 3.

will increase to 79.9 years for men and 85.1 for women¹².

It is also clear that the increase in the number of elderly people will increase the pressure on the public sector for long-term care. Age-related illnesses, which may be serious enough to make sufferers completely dependent on others, require long-term care (outpatient care, in long-stay units or in psychiatric units). Such care is not a matter for the “conventional” health system, but for the medical-social sector. The increase in the number of smaller and more unstable family structures could undermine the solidarity of family networks and make the provision of health and care within families more difficult to continue¹³.

For this reason, together with the amount of spending restraints, the European Union is promoting the idea of healthy aging. This proposal works on the idea that it is not the aging of the population *per se* that causes greater expense, but unhealthy aging. For this reason, the main recommendations relate to measures to promote healthy aging¹⁴.

People start aging the moment they are born. It is therefore important for them to have – as far as possible – good conditions in which to live their whole lives. What is at stake is a good start in life and a dignified end to life. Healthy aging starts long before retirement and is influenced by, amongst other things, living and working conditions and the availability of resources. If people realize this, the need for people to grow old responsibly follows logically. Responsible aging calls for lifelong learning (LLL). To this end, new strategies and policies for lifelong learning need to be drawn up at national, regional and local level in the health education sector. They must include all types of learning (formal, non-formal and informal)¹⁵.

Aging of the population affects healthcare in a double sense. It does not only imply, as indicated above, the increase in expenses, but also affects the professionals who work in the sector. As the population ages, so does the workforce. Between 1995 and 2000, the number of physicians under the age of 45 across Europe dropped by 20%, while the number aged over 45 went up by over 50%. For nurses as well, average ages are rising; in five member states nearly half the nurses are aged over 45¹⁶. In

12. Recent studies carried out in seven industrialized countries appear to confirm that, over the last decade, demographics have had an impact on the trend in spending equivalent to 1 % in volume terms. This rise is due to in equal measure to the overall increase in population and to aging. See ‘Healthcare,’ *supra* note 4, at 3.

13. *Communication from the Commission to the Council*, *supra* note 3, at 5.

14. *Id.*

15. Opinion 2011/C44/02, *supra* note 10.

16. Green Paper, *supra* note 11, at 6.

the coming years a significant number of healthcare professionals will be retiring. Due to this, if this new scenario of an aging demographic and long-term care demands a certain number professionals working, hiring is going to take place within a context of a stabilized or reduced active population.

Therefore it is important to consider the significance of human resources in the health sector in the European Union. In 2002 the number of people employed by the sector rose to 17.5 million across 25 states; that is to say 9.3% of the total workforce¹⁷.

(ii) Technological Progress

Technological progress also produces a double effect. It has a bearing on the increase in healthcare spending and that it implies difficulties in recouping the investments made; demanding as it does constant renewal and maintenance of equipment and devices. It is also true that this advance could represent a reduction in other costs. Regarding this, electronic healthcare systems can play an important role in dealing with these pressures by making the health sector more productive and providing better results with fewer resources¹⁸.

In fact, supply and demand will contribute to this higher spending. Health is an atypical economic sector, because the supply side — i.e. doctors — largely determines the demand, sometimes to the detriment of systematic evaluation of the real health benefits of innovations and their cost to the public. Moreover, today's patients are better educated and informed than ever before and are demanding the very latest treatments, or products such as food supplements which are claimed to be beneficial to health. They exert a pressure on doctors, which is particularly felt in countries where patients are free to shop around for health care. "This pressure on the demand side has a specific, measurable impact for medicines, as the most recently developed molecules are almost invariably the most expensive."¹⁹

(iii) Increase in demand

Finally, regarding what people often refer to as an increase in demand, the Economic and Social Committee has termed the *generation*

17. In Spain, the health system is the biggest employer in the state, employing 1,129,200 people. JM Aranaz et al., *Gestión sanitaria. Calidad y seguridad de los pacientes*, Díaz de Santos, Madrid, 2008, 3.

18. Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions of 30th April 2004, regarding E-health (towards better health care for European citizens: An action plan for a European e-Health).

19. 2001 J.O. (723) 6

effect. This refers to the fact that recent generations are accustomed to enjoying a higher level of healthcare than previous generations who did not have access to such healthcare.

As such, "it is quite conceivable that these factors may lead to a multiplier effect on healthcare expenditure occurring as these generations get older if people begin life with proper access to healthcare and continue to benefit from it throughout their active lives."²⁰

It is also interesting to note that there has been a growing trend to treat social problems as medical problems – While the approach to this factor is complex and necessitates further examination, it should not be overlooked, especially since European society is increasingly demanding the use of the precautionary principle. "All types of social insecurity (unemployment, precarious situations, stress, discrimination, pollution etc.) increasingly affect the state of health and healthcare spending, and create a growing demand to apply the precautionary principle."²¹

B. Public perception regarding health protection

Secondly, health protection is important in that the public considers it to constitute one of the most important public policies for its own well-being and security.²² For this reason the European Union is aware that the movement toward a more homogenous political and economical framework happens, inexorably, via common healthcare policies. The officials of the European Union understand that the participation of the public in the process of construction of this new Europe will only be possible if the public perceives the process as a means to measurable improvement in quality of life. Such perception is vital in ensuring support for the Union's evolution.²³

We are not, therefore, referring to an irrelevant or merely incidental common policy, but a policy that from economic, political and social standpoints, is essential to building a true European Union.

From a legal standpoint, this paper will assess the likelihood that the European Union develops a common framework for universal healthcare. We will discuss whether this option is really convenient, primarily

20. 2003 J.O. (C234) 37

21. *Id.* at 38.

22. Moreover, as has already been pointed out, the development of the social state has meant that the state itself and public services have turned into something additive for citizens, and this would be especially true of the provision of healthcare services.

23. Exemplifying the social and political importance of this matter is that health protection issues appear not only in rules issued by Parliament, but also in those European constitutions which were approved after the Second World War in Europe, and particularly after the fall of the Berlin Wall.

focusing on the economic and competition problems it could create. First, we will study whether such an alternative is real, and then whether it would be consistent with better public health protection of citizens of Member States.

From this essentially legal focus on the hypothesis we will conclude with an analysis of convenience, which we also deem necessary to be able to really address this issue in a thorough manner.

Problems deriving from the development of a common healthcare framework in the European Union are not a subject often addressed by scientific papers. In many cases the problems in the development of these common policies in the European Union are analyzed from a global perspective and not from a sector's perspective; meaning the conclusions drawn do not address industry-specific problems that arise from certain policies. The paradigmatic example of this would be health policy, which is of substantial importance as much for the people who depend on it for health protection as for the relevance it has on the economic market and GDP of Member States.

II. THE ABSENCE OF AN ADEQUATE REGULATORY FRAMEWORK

The European Union's advance toward the creation of a single European area has progressively gone beyond the realm of a single market economy. This has been possible from a legal standpoint due chiefly to the Maastricht Treaty. In this respect, EU policies relating to social matter demonstrate well that a mere economic union has gone beyond its initial aspiration. Thus, while the founding Treaty of the European Economic Community only contained some provisions relating to social matters (see Article 117 which contains the promotion of improved living conditions and working conditions of workers), the first EU policies focused upon the mere realization of the principles of free movement of citizens (mainly workers) and goods. It would not be until the eighties when the trend began to change. In that period, and above all, from the signing of the aforementioned Maastricht Treaty, two policies in community plans directly related to well-being emerged: (1) addressing research and technological development, and (2) environmental protection²⁴.

The Treaty of Amsterdam should also be cited at this point. It made

24. S Muñoz Machado et al., *La europeización de las garantías de los derechos y la universalización en Europa de algunas políticas de bienestar*, in S Muñoz Machado, et al., *Las estructuras del bienestar en Europa*, CIVITAS, at 320-21 (Madrid, 2000).

significant improvements in the sphere of social policies in which it is stated that social policy must not exist outside of the construction of the European Union²⁵.

Similarly, the common policy on social security led to the adoption of Regulation (EEC) No 1408/71, the Council of 14 June 1971 concerning the application of social security schemes to employed persons and their families moving within the Community, Council Regulation (EEC) No 574/72 of 21 March 1972 laying down detailed rules for implementing Regulation (EEC) No 1408/71 and Regulation (EC) No 883/2004 of the European Parliament and the Commission of 29 April 2004 on the coordination of social security systems. These standards, under the coordination of national social security systems, have allowed coordination of health policies (see, for example, the case of employee residents in a Member State other than their own who are to receive health care), which represents how Europe existed and still exists, especially in the Bismarck health models where there is a direct link between contributions and entitlement to healthcare²⁶.

The Union has been ambitiously expanding into areas beyond common economic policy. A previously existing regulative framework has made such expansion possible. However, regarding health policy, the regulatory framework does not allow such an advance, since the provisions contained in Community Rules are the first to limit such an alternative without extending the EU principle of subsidiarity beyond what initially seems possible. A plain reading of the constitutional laws provide good examples of this²⁷.

The Treaty on the Functioning of the European Union²⁸ in its current

25. Various authors have noted that this change in the criterion for the EU regarding social policy was motivated by the victory of the Labour Party in the UK, given that this Member State had traditionally been the one vetoing the attempted construction of a Social Europe. *See id.*

26. On the contrary, the models inspired by the Beveridge system or of a national healthcare care system do not match up with this connection between contribution to social security and the right to healthcare provision. Nevertheless, the majority of the European models were inspired at their outset by this relationship. For example in Spain the change in model came in 1986 with the Ley General de Sanidad (General Healthcare Law), and fundamentally, in 1994 with the new Ley General de la Seguridad Social (General Social Security Law). From that point, financing of the health system would be based, principally, on the collection of taxes and not on contributions to the Social Security System.

27. The subsidiarity principle from the Maastricht Agreement, constitutes a rule of operation of the European Union and, in particular, of the exercise of the communitarian competences. It is used to define the borders between the competences of the Member States and those of the European Union. To put it briefly, we can say that the same implies that the European Union will only take part in the case, and insofar as, the objectives of the attempted action cannot be achieved in an adequate manner by the Member States, due to the dimension or for the effects of the attempted action, affects the Union (Article 5.3 of the Treaty of the European Union).

28. Previously known as the Treaty establishing the European Community or more commonly known as the Rome Treaty.

form, following the modifications brought in by the Lisbon Treaty of 2007, contains several provisions on health and health policy. However, these forecasts limit themselves to dealing with cooperation and assistance to national policy. Without prejudice to this, we highlight public healthcare, given that article 168²⁹ stipulates for, along with the high level of human health protection, a development of common policies this matter: “Union action, which shall complement national policies, shall be directed towards improving public health, preventing illness and physical and mental diseases, and obviating sources of danger to physical and mental health.” In any case, as we can see, it is dealt with as a mere supplement.

Furthermore, paragraph 7 of Article 168 provides that “the union action shall respect the responsibilities of Member States for the definition of their health policy and for the organization and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health service and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4 (a) shall not affect national provisions on the donation or medical use of blood and organs”.

So while under the Treaty on the Functioning of the European Union stones are laid towards a legal framework regarding public health matter, it does not affect the management and delivery of health services nor the formation of Member States’ healthcare policies. Therefore, the impact on healthcare matters is basically nothing or, at most, extremely limited, given that national interests always take precedence over those of the community.

The two areas in which Article 168 is innovative and begins to suggest the pathway towards a common framework is in its content regarding the organs, blood and human substances and medicines, and the fact that paragraph 4 of that Law provide for the case that both the Council and the European Parliament may adopt measures that contribute to achieving the objectives set out therein. The Treaty of Maastricht also addressed the health field the Article 129³⁰.

29. Previously article 152 of the Rome Treaty.

30. “1. The Community shall contribute towards ensuring a high level of human health protection by encouraging cooperation between the Member States and, if necessary, lending support to their action. Community action shall be directed towards the prevention of diseases, in particular the major health scourge, including drug dependence, by promoting research into their causes and their transmission, as well as health information and education. Health protection requirements shall form a constituent part of the Community's other policies. 2. Member States shall in liaison with the Commission, coordinates among themselves their Policies and Programs in the areas' referred to in Paragraph 1. The Commission May, in close contact with the Member States, take SP, and stock such initiative to promote coordination.”

Common healthcare policy is limited to a mere competence to develop cooperation between member states and if necessary, to support their action. However, healthcare policy relating to public health does appear to have room to grow, which means that nowadays a true common healthcare policy can be discussed and this would, obviously, be related to public health.

Furthermore, the Charter of Fundamental Rights of the European Union also limits the sphere of influence. Thus, although the Charter places the protection of health in its header (Article 3), through the proclamation of the right to physical and mental integrity, Article 35 states, "Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection ensurer shall be in the definition and implementation of policies and all Union activities"³¹.

Finally we must include the revision to community law of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market, which excluded from its scope the area of sanitary services³².

In short, the regulatory framework does not seem to allow for, in principal, going beyond mere cooperation and support on the part of the institutions of the community on national healthcare matters. Along with this, we must not forget that the first steps the institutions did take were in this direction as delineated by the Maastricht Treaty and not with the intention to develop common policies that exceeded mere cooperation and support. As such it was not only the regulations which limited the development of a common policy but also the will of the community institutions themselves. Therefore, healthcare would only be addressed as and when it was related to the necessity of the economic market³³ and with a clear call not to go beyond what was a community competence of mere cooperation and support.

31. In the European Convention health takes second place although many of its prioritized objectives were either directly or indirectly related to health. See WM Kühn, *El modelo social instaurado por la Constitución Europea: análisis desde la perspectiva de la protección de la salud pública*, 14 REVISTA DERECHO Y SALUD 30 (2006). See also P Belcher et al., *Is health in the European Convention?*, 9 EUROHEALTH 1 (2003).

32. However some authors have indicated that this exclusion of healthcare activity is only a formal one and that it will not be long before this sector is incorporated into European Union law. See C. Baes, *La justificación del intervencionismo administrativo en el sector del medicamento: especial referencia a la autorización sanitaria*, Revista de Derecho y Salud, 21 NÚMERO EXTRAORDINARIO XIX CONGRESO 30-31.

33. Martin McKee et al., *The influence of European Community Law on National Health Policy*, 6 J. EUROPEAN SOCIAL POL'Y, 263-268 (1996).

In any event, this poses an obvious dilemma, given that it is one of the most important sectors with regards to the economy - how can healthcare remain outside of the common market? How do we reconcile the ideas that healthcare is a simply national (of the Member States) issue while professionals and patients are in free circulation in the sphere of the European Union?³⁴.

The gap between the common economic policies and a common healthcare area is ultimately unsustainable. That is why, little by little, the idea of developing, to a high level, health protection has developed. It already constitutes a common objective: the common market requires a move towards a common healthcare area. The advance is timid, due in part to a lack of legislative backing despite being established by Treaties. Even at the Member States level, the Union is moving this direction. The three main goals are that community policy integrate healthcare considerations which will work towards a reduction in the inequalities in health matters; that the EU play a strong role in healthcare at a global level; and that emphasis is placed on the promotion of health and the improvement of healthcare information³⁵.

The assumption that European economic integration is separated from the purely national responsibilities in health must be questioned. The health system is an important part of the economy, and it is impossible to regulate one of them without causing effects on the other. Restricting health policy to the scope of the Member States while fostering economic integration at the European Union does not create a clear or even significant separation³⁶. The free movement of persons, goods, services and capital also means the free movement of healthcare professionals, users, medication, technology and healthcare services.³⁷

Moreover, as the European Economic and Social Committee states,

34. The example of pharmaceuticals in this case is paradigmatic. Pharmaceuticals is one of the most regulated sectors by the European Union, and is legislated on heavily from patent protection to approval, distribution and marketing of medication, although pricing and prescription policies do remain the responsibility of the Member States themselves. Moreover, the Committee of the Regions has recently reported "the strategy does not address the issue of pharmaceuticals despite the far-reaching impact on patients and the public if the provisions in place in this area are considered solely as a facet of industrial policy and not in connection with health." See Opinion of the Committee of the Regions of 9 April 2008, on "The white paper — Together for health: A strategic approach for the EU 2008-2013".

35. In 2004 the Commission organized an open consultation which asked about the future action of the EU in the healthcare sector. Europa, http://ec.europa.eu/health/ph_overview/strategy/reflection_process_en.htm. In 2007, a second consultation was carried out regarding operating factors and the priorities of future strategy. Europa, http://ec.europa.eu/health/ph_overview/strategy/results_consultation_es.htm.

36. See The European Union and Health Services: The Impact of the Single European Market on Member States. (2002).

37. See *id.*

although “the organization and management of healthcare systems remains, even under the Lisbon Treaty, the task and responsibility of the Member States, and that the EU institutions merely support the Member States in this task. However, as the European Charter of Fundamental Rights states, the right to access healthcare must be ensured.”³⁸ The lack of Community competence with regards to the social security systems does not mean that the Community should remain indifferent to conceptual and policy debate on these issues, of which healthcare presents multiples.

On the other hand, if the free movement of citizens was one of the basic principles under which the European Union was created, we can state that this principle is not satisfied until there is a common healthcare policy. The relationship between freedom of movement and the common healthcare framework is inseparable³⁹.

To conclude this review of the legislation we must cite two documents which are not in the strictest sense regulatory but summarize the objectives and strategic actions which the European Union proposes to undertake in the future with regards to the healthcare sector and the provision of healthcare services.

Firstly, the Tallinn Charter which aimed to strengthen healthcare systems in Member States arose from a meeting of community healthcare minister in Tallinn from the 25th to the 27th of October 2009. The Charter not only proclaims the fundamental right to the highest attainable standard of health, but also finds it unacceptable that a person can become impoverished as a result of suffering from an illness.⁴⁰

Secondly, the Commission’s white paper, “Together for Health: A Strategic Approach for the EU 2008-2013” from the 23rd October 2007. Here, although the commission recognizes that Member states hold the main responsibilities regarding healthcare policy and the provision of

38. Opinion 2011/C44/02, *supra* note 10.

39. As Pemán Gavín says the free movement of people is certainly favored by recognizing the right to public healthcare in the place of stay and reduce or simplify the procedures and formalities required to benefit from this right, certainly trips and stays to other Member States are eased if the inherent risks of sudden health issues arising and related costs or procedural matters are eliminated when outside one’s country of residence. Juan Pemán Gavín, *Asistencia sanitaria pública y libre prestación de servicios. Sobre la libre circulación de pacientes en el espacio comunitario europeo (a propósito de la sentencia Smits y Peerbooms del Tribunal de Justicia de las Comunidades Europeas)*, 160 REVISTA DE ADMINISTRACIÓN PÚBLICA 123, 126 (2003).

40. The commission indicates however mortality rates show that in all the Member States there is sometimes a very close link between people’s health and their position in society. This is a reflection of low income levels, which mean that some people restrict their consumption of health products; this is particularly true when a large share of the cost has to be borne by patients, as in the case of dental or optical care, or when patients have to pay all or part of the cost of the services concerned themselves and seek reimbursement afterwards). See *Communication from the Commission to the Council*, *supra* note 3, at 10.

healthcare to European citizens, the role of the Union does not mirror or duplicate these activities. There being fields in which the Member States themselves would not be effective, there still is an indispensable need for cooperation at a community level. This would be the case, with public health (pandemics or bio-terrorism) as with activities related to the free movement of merchandise, services and persons.

The normative basis of the strategy proposed through the White Paper is the aforementioned Article 168 of the Treaty on the Functioning of the European Union (formerly Article 152 of the establishing Treaty). Through the Treaty, the Commission intends to define the first Community strategy on health with a coherent framework, which will guide the activities of the Union. As a priority for the coming years, four major principles in support of three strategic objectives are proposed.

The principles are the following:

- The principle of sharing, whereby the development of a Community policy in the field of health must be based on shared values.⁴¹
- The principle of prosperity, so that investment in health should not be viewed as a cost but an investment in prosperity and productivity.⁴²
- The principle of mainstreaming, so that health policy is addressed in other policy areas with which it is interconnected, such as environmental or research.
- Top global leadership so that the Community institutions occupy a central role in this field not only in Europe but globally and that health policies constitute a reference point throughout the international sphere. The European Union must assume a collective leadership standing worldwide.

As mentioned earlier, these principles outline three strategic objectives:⁴³

- The promotion of good health in a society where aging is a characteristic feature. This strategy aims to develop the concept of healthy aging which was referred to earlier.
- The protection of citizens against health threats, especially in regard to new technology risks of climate change, displacement of people and trade and terrorist threats in form

41. They are dedicated to ideas such as universality, access to quality health care, equity, solidarity, empowerment of patients and citizens in general, and reducing inequalities.

42. A healthy society is a society able to meet the challenges of prosperity involved in the XXI century.

43. These strategic objectives will be subject to review in 2013.

of bioterrorism. Within this strategic objective patient safety policy is included.

- The promotion of dynamic health systems and new technologies.

III. COMMUNITY POLICIES IN THE FIELD OF HEALTH: LIST OF SOME SIGNIFICANT EXAMPLES

As examples of progress within the health sector, some projects relate both to the provision of healthcare services and the management and coordination of them such as a common electronic medical record a European health card, and improving standards for organ transplant and donation.

A. Common electronic medical record

In the first place is the project of electronic medical records, despite lacking effective development even though it has real importance towards creating a framework enabling common healthcare. This project aims to develop the regulation and technology towards shared digital medical records or at the least towards a set of basic medical data being shared in the European Union. This initiative has been developed through the project epSOS (European Patients Smart Open Solutions). The project is funded by the European Commission under the Competitiveness and Innovation Program (CIP). The same project also proposes the development of electronic prescriptions (*ePrescription*)⁴⁴.

This project, currently involving nine Member States, has the important collaboration of private sector representatives, and may constitute an important step in building a common space to the extent that the sector will be able to deliver health care from any Member State with access to shared common data and basic clinical data on patients. However, it is also true that regulatory diversity between Member States on issues such as the necessity or otherwise of a written protocol of informed consent for the professional to access such data may be complicate, from a legal point of view, the project.

It is true that the rules of the Member States on data protection is a common legal framework based on Directive 95/46/EC of the European Parliament and the Council of 24 October 1995 on the protection of private individuals as the processing of personal data and the free

44. European Patients Smart Open Services, *available at* www.epsos.eu.

movement of such data, which has been incorporated into national law. However, in regard to health-related data, the absence of a European charter of patients' rights does not, therefore, allow us to talk of genuine common regulation on personal health data and medical records. There is a common regulation regarding data protection, but no specific regulation on health data which, moreover, should have special protection because of the sensitivity of its contents.

Within the field of shared digital records, we also emphasize the Commission Recommendation of 2 July 2008, on cross-border interoperability of electronic health record systems (2008/594/EC). This recommendation considers that one of the strategies to move toward the common area healthcare is the standardization of operating systems of digital medical records used by the different Member States.⁴⁵

The European project is not limited to a mere homogenization of technical systems but goes beyond this and tries to aim toward a semantic homogenization⁴⁶ and, to this end, intends to develop a system of concepts of sustainable reference. In this regard, we note that cross-border healthcare presents not only technical challenges, which are probably the easiest to overcome, but, moreover, cultural, social and linguistic issues. Not only are the physicians attending cross-border citizens intended to access specific data from the common area, but they are also supposed to complete the data in the European registry using the terms specific to the form.

In addition, the Commission also lends a lot of importance to the legal problems which could derive from such a project because interoperable medical records systems increase the risk of accidental disclosure or easy distribution of patient data to unauthorized persons, allowing wide access to a collection of personal data regarding patient health, compiled from different sources, and throughout a patient's lifetime. This requires the establishment, by Member States, of a comprehensive legal framework for interoperable electronic medical

45. It states that:

"[The] lack of interoperability of electronic medical record systems is one of the major obstacles for realizing the social and economic benefits of eHealth in the Community. Market fragmentation in eHealth is aggravated by the lack of technical and semantic interoperability. The health information and communication systems and standards currently used in Member States are often incompatible and do not facilitate access to vital information for provision of safe and good quality healthcare across different Member States."

2008 O.J. (L 190) 37, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:190:0037:0043:EN:PDF>.

46. Common semantics of health, in the terms the recommendation employs.

record systems.

The proposal by the Recommendation is that a global interoperability of eHealth in Europe be developed by the end of 2015. It can be said, therefore, that European electronic medical records are not only a major challenge for the quality, safety, and efficiency of European health systems, but are also one of the strategies essential for progress toward a common area of health.⁴⁷

Thus, the connection between e-Health and its main issue, European medical records, and a common healthcare area, is indivisible. The technological challenge is, ultimately, the framework's main issue.

Furthermore, this community policy is being carried out with the same development field applied to health with telemedicine. In this regard, we can highlight the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the regions of 4 November 2008, on telemedicine for the benefit of patients, healthcare systems and society.⁴⁸ The Commission states the view that the community's progression with regard to telemedicine, the provision of healthcare services at a distance, can help improve the lives of European citizens – both patients and healthcare professionals – while tackling the challenges to healthcare systems. Telemedicine can improve access to specialized care in areas suffering from a shortage of expertise, or in areas where access to healthcare is difficult. Telemonitoring can improve the quality of life of chronically ill patients and reduce hospital stays. As the Communication states:

The benefits go beyond improving patient care and healthcare system efficiency. Telemedicine can also make a significant contribution to the EU economy. This sector, where European industry – including thousands of small and medium-sized

47. An action plan for a European e-Health Area states that the European Union must move towards a European eHealth Area, giving eHealth a key role in the European Union's policy of developing the eEurope strategy. Such progress is motivated, according to the Communication, by the idea of the increasing movement of patients and health professionals within an internal market functioning to a better level. *e-Health – making healthcare better for European citizens: An action plan for a European e-Health Area*, at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2004:0356:FIN:EN:PDF>. Similarly it is stated by the European Economic and Social Committee that access to healthcare in another Member State offered to each citizen must be based in particular on a European medical file and health booklet that have been properly updated and to which medical professionals and patients themselves have access. See *Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare*, at http://ec.europa.eu/health/ph_overview/co_operation/healthcare/docs/COM_en.pdf.

48. *On telemedicine for the benefit of patients, healthcare systems and society*, at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0689:FIN:EN:PDF>.

enterprises (SMEs) – is well placed, has been expanding rapidly in the past decade and is expected to continue to grow at a fast pace.⁴⁹

However, possibilities to develop these telemedicine projects come into conflict with important legal issues, as indicated by the Commission, which emphasizes the lack of legal clarity – in particular with regard to licensing, accreditation, and registration of telemedicine services and professional liability, reimbursement, and jurisdiction – as being a major challenge for telemedicine and, in particular, for teleradiology. The cross border provision of telemedicine services also requires legal clarification with regard to privacy. Only a few Member States have clear legal frameworks enabling telemedicine.⁵⁰

In any case, the onus for making this initiative a success rests mainly with Member States. They bear the responsibility for the organization, provision, and funding of their healthcare systems. Telemedicine will only realize its full potential if Member States actively engage in integrating it into their health systems.

B. European Health Card

Secondly, through the European health card project, the citizens of the European Union (and also those of Iceland, Liechtenstein, Norway and Switzerland) can get the same health care as citizens of the Member State they are visiting. However, the card is not valid if the reason for moving is to receive medical treatment, and, in this case, you need specific prior authorization of the State where the citizen is insured. Thus, the card would replace the E-111 form but not the E-112 form.⁵¹

49. *Id.* at 2.

50. In some Member States, for a medical act to be legally recognized as such, the physical presence of the patient and the healthcare professional in the same place, is required; this is a clear obstacle to the use of telemedicine.

51. The background to this draft common policy is from the European Council in Barcelona in March 2002, in adopting an action plan for mobility and the Communication from the Commission to the Council, the European Parliament, the Committee Economic and Social Committee and the Committee of the Regions of 13 February 2002 on the Action Plan for Skills and Mobility. *Commission's Action Plan for skills and mobility*, at http://youth-partnership-eu.coe.int/youth-partnership/documents/EKCYP/Youth_Policy/docs/Employment/Policy/Com_Actionplan_Skills_Mobility.pdf. In this, the Commission states that "social security co-ordination should be modernized and simplified through the extension of the material and personal scope of Regulation 1408/71 and by simplifying its wording and implementation." In this respect an EU-wide health card should be introduced, aimed at transforming the relevant European paper forms into an electronic card. And thus, "card holders will be able to claim access to health care immediately in a Member State other than the one where they are insured, the latter being, nevertheless, responsible for the cost." *Id.* at 16. Subsequently, Decisions numbers 189, 190 and 191 of the Administrative Commission on Social Security for Migrant Workers (CASSTM) on June 18, 2003, adopted the necessary concrete measures to implement such a project. *Available at*

However, this project is not actually connected to healthcare itself, nor is the previous project of shared medical records. But rather, it is inserted into the process of repayment for medical aid received and paid for in another state member. It facilitates reimbursement procedures through a single instrument – the card – instead of having the patient complete an official form. Rather than a medical assistance project – although it has effects in this field – it would constitute a project setting out the common space in terms of Social Security.

C. Organ donation and transplantation

Thirdly, the Directive of the European Parliament 2010/45/EU and of the Council of 7 July 2010, directs development of standards of quality and safety of human Organs Intended for Transplantation,⁵² an initiative taken under the temporary Spanish presidency of the Europe Union.⁵³ The initiative had the intention of starting the common healthcare framework for Europe with regards to organ donation and transplantation by developing the standards of quality and safety at each step of the transplant process, from the very donation up to the transplant or disposal⁵⁴. Likewise, the law is intended to contribute indirectly to combating organ trafficking through the designation of competent authorities, the approval of transplant centers and the establishment of conditions for obtaining and tracking systems.⁵⁵

Although the health sector can hardly be outside of a common economic policy in the European Union, it is a matter that remains largely in the hands of Member States and the European integration process itself has brought a growing concern for the strengthening of European welfare

ec.europa.eu/social/BlobServlet?docId=2156&langId=en. Each Member State is responsible for the production and distribution of the European Health Card in its territory, and the institution that issues it determines its validity period.

52. See R. Marazuela & R. Matesanz, *La Directiva 2010/53/UE sobre normas de calidad y seguridad de los órganos humanos destinados al trasplante*, 21 REVISTA DERECHO Y SALUD 79, 79-84 (2011).

53. As a precedent of this rule, the Communication from the Commission to the European Parliament and the Council of 30 May 2007, "Organ donation and transplantation: Policy actions at EU level" must be cited in proposing to adopt the directive. *Organ Donation and Transplantation: Policy Actions at EU Level*, at http://ec.europa.eu/health/ph_threats/human_substance/documents/organs_com_en.pdf.

54. A precedent of this Directive, the Directive 2004/23/EC should be cited of the European Parliament and of the Council of March 31, 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of Human Tissue and cells.

55. Note the difficulty of adopting a rule with this content, especially regarding the various criteria that Member States maintain about the requirements to be met by donors and regarding previous diseases as well. Therefore, although in countries where there is a significant number of donations it is possible to maintain very strict criteria over the safety and quality of the organ, in countries where such number is much lower, this security policy and quality is geared toward permissiveness.

structures⁵⁶, welfare which has a big impact on the health of citizens. Little by little, the EU has been consolidating certain common healthcare policy areas, including the organ donation and transplantation regulation and the project, still in development, regarding the single digital medical record.

The common healthcare policy has made its way through soft law, although it has not found real support in the Treaties establishing the European Union.

IV. DIFFERENT EVOLUTION OF PUBLIC HEALTHCARE MATTERS

The initial reluctance to develop common healthcare policy that was expressed by the Maastricht Treaty itself, underwent an important change with the health crisis of the late twentieth century and, in particular, what was commonly known as the *Mad Cow Crisis*.⁵⁷ Crises such as that cause an awareness in the European Union of the real importance of creating a common framework on public health holds⁵⁸, which had a normative or regulatory basis in the Treaty of Amsterdam. To be specific, article 152 represents an increase in the policies which the Union may now make in this field and, above all, in the public health sector (standardization of matters concerning human organs, specimens of human origin, blood and blood products, and veterinary public healthcare matters).⁵⁹ In the same sense, the Treaty on the Function of the European Union, through the message provided by the Treaty of Lisbon, states that, “The Union and the Member States shall foster cooperation with third countries and the

56. Machado et al., *supra* note 24, at 404.

57. Spongiform encephalopathies are a group of diseases that affect both humans and animals. They have universal transmission and a very long incubation period (maybe decades), but once diagnosed evolve fatally in a few months. They are caused by an infectious protein that accumulates intra-cellularly in the central nervous system and have a rapidly progressive dementia effect. In 1986, the first cases appeared in the UK and increased rapidly to more than 180,000 cases. The disease may have affected another one to three million cattle, many of which were diverted from human consumption before developing symptoms. As in other so-called emerging diseases, little is known about the causative agent involved. It is even unknown in the case of the new variants, with significant knowledge gaps in relation to the exposed population, the infectiousness, the incubation period or possible genetic susceptibility. The various scenarios for transmission are not well known. See Jose Maria Arteagoitia Axpe, *Vacas locas 8 años después, gripe aviar 4 años después, gripe A hoy: La enfermedad de Creutzfeldt-Jakob ¿qué ha pasado desde entonces?, ¿qué se hace en estos momentos?*, 7 REVISTA DE ADMINISTRACIÓN SANITARIA DEL SIGLO XXI, 361, 361-362 (2009).

58. See, e.g., 1998 O.J. (L 268) 1 (setting up a network for the epidemiological surveillance and control of communicable diseases in the Community, among them diseases found to be caused by unconventional agents). See also, 1999 O.J. (L 28) 50 (regarding the communicable diseases to be progressively covered by the Community network).

59. See CARMEN RODRÍGUEZ MEDINA, *SALUD PÚBLICA Y ASISTENCIA SANITARIA EN LA UNIÓN EUROPEA. UNA UNIÓN MÁS CERCANA AL CIUDADANO* (Comares 2008) (Sp.) (regarding the evolution of public health policies in the European Union).

competent international organizations in the sphere of public health.”

Within this evolution towards a common framework in the field of public health, it is worth calling attention to the European Center for Disease Control and Prevention. It is headquartered in Stockholm and is an organization whose mission is to identify, assess, and communicate threats to human health from infectious diseases⁶⁰.

This objective of promoting prevention policies has become ever more important and relevant as our healthcare systems begin to present their financial problems caused by relentless increases in demand and changes in health technology.

Therefore, the evolution of these projects and public healthcare regulations demonstrate how the European Union, in its development, is following the path that countries have previously had to traverse. In this way, there has been progress in relation to the right to health protection relating to public health. But it appears that there remains something lacking in the provision in relation to the other area, healthcare law, which is only envisaged in the field of the social security system and in relation to the protection of the working population⁶¹.

V. DIFFICULTIES IN DEVELOPING A COMMON HEALTH POLICY: ANALYSIS OF REASONS

As stressed, progress made towards advancement in these fields has come across a number of difficulties in the field of health protection. Several authors and individual European Union officials have provided various reasons for these difficulties.

A. Absence of a single model in the Member States

While all European models are based on the principles of solidarity, fairness and universality, the management and delivery of health services was implemented through different models, mainly the Bismarck model or insurance model -Germany, France, Holland, Belgium and Luxembourg - and the Beveridge model or national health system (tax-based universal system or national health system model) – UK, Spain, Italy, Greece, Portugal, Sweden, Norway, and Denmark, as well as those using mixed

60. This Center was established in 2005 with the aim of fighting against infectious diseases. Its mission is to identify, assess and communicate threats to human health arising from these diseases. Thus, one of the specific areas in which the Center has been working is in the field of vaccines, with the aim of developing a European policy on vaccination. EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL, <http://www.ecdc.europa.eu>.

61. PS Ortiz de Elgea Goicoechea, *La asistencia sanitaria en la Unión Europea ...*, cit., 65.

models.

The significant differences of both models make it difficult for them to coexist harmoniously. The Bismarck model (also known as insurance system) is characterized by the fact that the health system, both in regard to funding and the right to benefit, is linked to the employment relationship so that citizens who pay into Social Security are eligible for benefits through health insurance. The provision is secured by the payment of mandatory fees. Some Member States that use the model also incorporate a system of reimbursement in which the citizen makes the payment for healthcare provision and then is reimbursed by the public system.

By contrast, in the Beveridge model, neither the funding nor the right to health benefits is linked to any employment relationship, but the system is funded from the general state budget, i.e., the citizens' tax contributions.

The role of the private health sector is also different in the health systems. While in some States healthcare is provided from the public system, there are others in which there is significant participation by private health insurance through supplementary insurance.

These models have problems from the point of view of the workload. National health systems can, in theory, more easily control spending (as it is inherently budgetary), but the pressure of demand may cause longer waiting lists the size of which reveals a real inadequacy of the service. In insurance systems, which in many cases separate care providers from the funder, an increase in demand or costs results in an increase in expenses. This increase can be unsustainable to public finances; however, in resorting to increasing revenues or cost-cutting measures, they often face the opposition of stakeholders, especially given the difficulty of choosing the importance of requirements to be met⁶².

This difference in national models has a substantial impact on the geographic movement of citizens, as neither the right of access to the system nor form of management of access and benefits are the same in all Member States⁶³.

However, it is no less true that the systems of all Member States share some common principles of solidarity, equity and universality.

62. See *Communication from the Commission to the Council*, *supra* note 3, at 12-13.

63. As correctly noted by the European Economic and Social Committee, "the efficiency and proper use of healthcare services in a cross-border context require that healthcare organizations in the different countries complement and counterbalance each other in terms of their capacity with respect to technical services and human resources, medical equipment, and determining the responsibilities of service providers. See Opinion of the European Economic and Social Committee of December 4, 2008, *supra* note 48, at 5.

B. Continuing reformulation of care models

The relentless rise in health expenditure is causing Member States to rethink the reforms that should be introduced in order to maintain the principle of universality in their healthcare system.. One concept is clear: reforms that seek only to revise the old ways of managing and providing service are not enough.⁶⁴

Furthermore, the idea of achieving the greatest efficiency at the lowest cost also affects the very basis of healthcare as a public policy. This affects the development of not only the way a future European system comes about but also starts to bring up the question of whether a public health policy is really justified. If public intervention in healthcare does not have justification within the two arguments which have traditionally been used in relation to this question- the redistribution argument and that on the improvement of welfare⁶⁵- spread then a much bigger change needs to occur.

What is certainly true is that what the European Union would always have left, as common policy, is the coordination and control of the private healthcare policy, that is to say the private sector. However, the control would merely be economic, based in the guarantee of competition, rather than political, and more importantly, would not allow progress towards a single social Europe in which health takes on a leading role. Thus, it is difficult to develop a common framework on health policy for the community, when the very foundation of public intervention in health care is brought in to question.

The very re-planning of the different health care models in search of a new model which seeks to curb the relentless increase in expenses slows down the creation of a common healthcare framework. While the Member States themselves cannot define their models, it is difficult for the European Union to be able to develop a single model for healthcare. This

64. G López i Casanovas, *Las estructuras del bienestar en el sector de cuidados de la salud*, in Machado et al., *supra* note 24, at 677.

65. As regards the first argument, it is based on the idea that government intervention in the health sector is one element in favor of redistributive task being entrusted to the welfare state, so that those who cannot economically meet the health care requirements may go to the public system. Health is considered one of the values to promote in today's society, so that the financial capacity of citizens not to influence it. This argument would link also reformulating the concept of public service has suffered from the crisis of the welfare state and after implementation of the principle of competition brought about by the development of the European Union. Public participation in the health sector would seek to cover an economic sector that would not be completely served by private companies not to be profitable. Be avoided, with both ideas, to develop a society of two speeds. On the other hand, the second argument is based on the idea of a single insurance pool, so that citizens, unable to know beforehand what will be the evolution of their health, they find it beneficial to create a sort of public insurance health care, where some meet other spending. It includes an interesting reflection on both arguments.

is only exacerbated further by the economic crisis, given that the debate now centers on the sustainability of the public systems themselves, the options in the face the scarcity of public resources being much more limited. In this regard, the option that seems most viable in many states is the co-payment option. Nevertheless, some Member States, including Spain, do not consider this to be a feasible option. These states prefer to take other measures to maintain the free system, such as the incorporation of more effective ways of management, especially regarding staff to reduce spending, and development of drug policies that promote the prescription by physicians of generic drugs, reducing pharmaceutical expenditure, which has one of the greatest impacts on public health spending.

In the same vein, many Member States have not defined what the role of the private sector should be in the healthcare system; that is whether tax funds should pass into the private sector, which would allow the private sector to support that of the public.

C. Diversity between therapeutic practices

There is a heterogeneous nature to medical treatment. This is the case, for instance, with regard to childbirth. The perinatal mortality rates in France and the Netherlands are fairly similar (8.2% and 8.4% respectively in 1996); yet, while in France most children are born in a hospital, almost a third of births in the Netherlands take place at home (although hospital births have become much more common in the last 30 years). It is therefore difficult to draw the *a priori* conclusion that one of these methods is “better.” There can also be regional differences within the same country, not only with regard to the methods or protocols adopted but also in terms of the apparent efficiency of health care services or techniques (which can, for example, be measured in terms of the post-operative mortality rate).⁶⁶ Such diversity has a further importance regarding the information that the practitioner should disclose to a patient regarding the provision of healthcare they may receive in other countries.

D. The language barrier

This barrier is more prevalent in the health sector since the development of a common healthcare area demands sharing information, not only for the patient but also for services, treatment practices, and pharmaceutical principles. It is true that coding can reduce the problem.

66. See *Communication from the Commission to the Council*, *supra* note 3, at 12.

However, the fact remains that encoding does not completely solve the issue, because beyond the code some essential information does not code properly. Additionally, management and election codes are always necessarily influenced by a cultural factor, so that while the code system may be unique, the criteria to which they are interpreted may differ.

E. The risk of the movement of healthcare professionals

Free movement of students and workers helps to ensure that health professionals go where they are most needed. But health professionals move for a variety of reasons - to achieve improved career and training opportunities or for better pay and working conditions-. Mobility can affect disparities –positively or negatively- within and between countries. In this context, some Member States may be unwilling to risk investment in training more health professionals if there is poor retention and return on the investment⁶⁷. Member states will not create incentives to train doctors and other professionals in the public sector if a large proportion of them are probably going to emigrate⁶⁸.

Also, the approval of national health systems and the creation of a genuine common health would affect the Member States in which the salaries of health professionals are lower, like the Eastern States and much of the Mediterranean States, including Spain, Portugal, or Greece.

F. The impact the development of a single market could have on the GDP of Member States

This situation has additional significance in the light of the economic crisis. Their impact assessment shows that the additional costs of treatment arising from these proposals are not likely to be such as to undermine the sustainability or planning of health systems overall. This is because citizens are only entitled to be reimbursed for healthcare that they were entitled to at home, so Member States only have to pay for healthcare that they would have had to pay for in any case. The impact assessment estimated that the additional costs of treatment would be a small fraction of one percent of overall health expenditures, and far outweighed by the benefits⁶⁹.

What could have an impact are the difficulties some Member States

67. Green Paper, *supra* note 11, at 9.

68. F Silió Villamil, et al., *Impacto de las políticas de la Unión Europea sobre los sistemas sanitarios*, *op. cit.*, 375.

69. Communication from the Commission of 2 July 2008, about a Community framework on the application of patients' rights in cross-border healthcare, 9.

would face in satisfactorily treating their own citizens if they have to also attend to a significant demand from cross-border patients, and, especially, in the respect to the most advanced therapies and treatments not available in the home countries of these patients.⁷⁰

It is also been noted that the lack of systems to allow the sharing of health information poses a problem, especially patients' medical records. However, as previously mentioned, it seems the different projects set up by the European Union may address this problem.

Therefore, it can be argued the EU has already moved towards a single European policy concerning public health. However, is it possible to say that the same applies to management and delivery of healthcare? Apparently not. While the achievement of a high level of health protection constitutes a common objective for the healthcare field, the regulation and management of healthcare services is a domestic matter for each of the member states about which there is no standardization across the European Union.

This absence of a common healthcare market is complicated further given the fact that the common market of people, goods, and services developed under the European treaties has had a significant impact on healthcare activities.

In short, the development of a common health framework may have unintended problems, which, in a situation of economic crisis, can have an irreparable effect on several States. Although, as illustrated by the Biomed project, the creation of a European health system would greatly boost the development of a European list of services which details the free choices for citizens. However, this development would seem to have a strong impact on Beveridge systems, leading to resistance in the Member States.

Thus, it does not seem feasible, neither the full integration of health services at a European level, nor the exclusion of national health systems from the European Single Market. The third option, to adapt to the situation, does not provide easy solutions. Similarly, doing nothing is not a sensible option⁷¹.

G. Equity issues for national health systems

The free movement of patients that comprises the creation of a common healthcare framework has implications for inequity, as it tends to further benefit those less ill, those who have more training and the

70. *Id.* at 10.

71. PS Ortiz de Elgea Goicoechea, *La asistencia sanitaria en la Unión Europea ...*, cit., 72.

wealthy, as these groups are better articulated and have greater trust and knowledge of the services they need and demand. Furthermore, they are aware of their rights and are more familiar with foreign travel, can more easily pay the transport costs and advance the money to cover medical expenses pending the subsequent reimbursement⁷².

Moreover, despite the fact that the patient's mobility is often sold under the label of greater choice of provider and treatment by the European citizen, the fact is that in practice it can only benefit the privileged social strata.⁷³

VI. THE COURT OF JUSTICE AS A TRUE PROMOTER OF THE COMMON AREA HEALTH: THE CASE OF HEALTH TOURISM.

The Court of Justice of the European Communities has built a strong doctrine on the common health market or, in particular, on the free movement of patients, in which it refers to as so-called "medical tourism" and in general to cross-border healthcare.

It is important to define both the seemingly informal term "medical tourism" and the concept of cross-border healthcare because it should be understood that the two are not the same. The former should be constrained to those cases in which the patient travels to another Member State within the European Union with the purpose of receiving medical services. The exclusive motive for making the trip is to receive the medical service.⁷⁴ By contrast, the term cross-border healthcare is more general and may include both the case in which the purpose of traveling is to receive health care as well as those cases in which the need for assistance arises more or less unpredictably, such as while traveling for leisure or business..⁷⁵

72. W Palm & IA Glino, *La regulación de la movilidad de pacientes en la Unión Europea: entre libre circulación y coordinación*, 7 REVISTA DE ADMINISTRACIÓN SANITARIA DEL SIGLO XXI 588 (2009).

73. *Id.* at 589.

74. Barrios Flores reminds us that the phenomenon of medical tourism is nothing new. Private health tourism has existed since the dawn of humanity. Whenever a person or a community needed to be healed they went to the places and people offering care. In Greece, numerous temples were erected under the invocation of Asclepius / Aesculapius, to which pilgrims flocked in search of a cure for their illnesses. See Lf Barrios Flores, *Europa y sanidad pública: el fenómeno del turismo sanitario*, 14 DERECHO Y SALUD 77 (2006).

75. The Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare states that 'cross-border healthcare' means healthcare provided or prescribed in a Member State other than the Member State of affiliation. However, the same Directive does not use the term "medical tourism" because European Institutions have tried to show that the new regulations are not intended to encourage European Union citizens to travel with the exclusive purpose of receiving medical treatment outside their country of affiliation, but to ensure that any EU citizen receives healthcare regardless of which Member State they should find themselves in, as a necessary demonstration of this principal of free circulation.

On the other hand, the Court of Justice uses the phrase “the free movement of patients” to describe cross-border healthcare, both for care that arises from an unpredicted need as well as care that received on a trip for specifically the purpose of receiving medical treatment outside their country of affiliation.⁷⁶

Finally, we exclude from the discussion the case of free movement of patients in the form of medical tourism that occurs at the patient’s own expense. Here the citizen does not intend to receive health care under the public system, but instead the person moves to another EU state with the express purpose of receiving health care at their own expense. This refers to cases where someone who needs some type of healthcare makes use of his contractual freedom and the free provision of financial resources to receive healthcare from clinics or hospitals offered by professionals based in another State.

The latter does not pose a problem as it is clearly linked to the free provision of services based, as is well known, in the Treaty on the Functioning of the European Union. This is one of the fundamental freedoms established under the European Union. We must recall that the free provision of services covers not only the movement of businesses and professionals to Member States other than their own, but also the movement of the clients and customers of those very services.⁷⁷

The doctrine consolidated by the Court of Justice comes from numerous cases arising from complaints by citizens against their home states for reimbursement of expenses incurred outside the State of affiliation..⁷⁸

The Court has created a doctrine that favors cross-border healthcare, as it believes that the development of common health policies is one of the fundamental aims of the European Union, and should not be limited to a single economic market.⁷⁹

76. The term for the free movement of patients first appeared in the European Union Court of Justice in Case C-158/96, *Raymond Kohll v. Union des Caisses de Maladie*, 1998 E.C.R. I-1935. Although not in the text of the resolution, the term is mentioned in the conclusions drawn by the Attorney General.

77. J Pemán Gavín, *Asistencia sanitaria pública y libre prestación de servicios* ..., cit., 124.

78. The Court of Justice of the European Communities Rulings: Case C-444/05, *Stamalelaki*, 2007, ECR I-3205; Case C-145/03, *Keller*, 2005, ECR I-2548; Case C-56/01, *Inizan*, 2003, ECR I-12423; Case C-385/99, *Müller-Fauré and van Riet*, 2003, ECR I-4539; Case C-157/99, *Smits and Peerbooms*, 2001, ECR I-5509; Case C-368/98, *Vanbraekel*, 2001, ECR I-5382; Case C-120/95, *Decker*, 1998, ECR I-1871; and Case C-158/96, *Kohll*, 1998, ECR I-1935. A summary of this doctrine of the court can be found in JM Antequera Vinagre, *Las sentencias sobre servicios sanitarios recibidos en países distintos a los de residencia: la libre circulación de pacientes en la Unión Europea. Revisión e implicaciones*, 7 *Revista de Administración Sanitaria del Siglo XXI*, 603-10 (2009). See also, W Palm & IA Glinos, *supra* note 73.

79. This is recognized, in *United Kingdom v. Commission*, July 12, 1996, which states that “none of the documents before the court supports the argument that the commission’s exclusive or main purpose was of

For the Court, although the organization and management of health care systems is the responsibility of Member States, such systems must be in harmony with the internal market legislation that allows the free movement of both patients and professionals. In this way, a genuine right to cross-border healthcare throughout the European area is enshrined under the principles of the European Union, although with some specific limits. This right allows EU citizens to apply for reimbursement of expenses incurred in another EU state, in which assistance was provided from their affiliated states. Thus, without confirming that European citizens can receive healthcare in the place of an unconditional right, nor excluding the possibility of national legislation being introduced that could limit or give conditions to this right, the need to examine the guidelines regarding the freedom of provision of services as outlined by the Treaty and the jurisprudence of the Court is thrown into sharp relief.⁸⁰

The doctrine of the Court of Justice could be summarized in the following points:

- Health care is a service for the purposes of community law, irrespective of whether it is a hospital or not and whether or not the national system is based on the Bismark reimbursement model..
- No one can be denied permission for treatment in another state if there is medical indication for it according to international standards; even if the international standards may not be the standard in the country of origin, nor if the treatment in the home state would be provided with undue delay.
- The requirement of prior authorization for reimbursement may constitute an obstacle to the rights of citizens.
- This requirement is, however, permissible in the case of hospital services,⁸¹ given the need for planning to ensure sufficient and permanent access to a balanced range of high quality hospital care, and to control costs and prevent the possible waste of financial, technical and human resources.
- It is also required if the procedure is clearly regulated, the matter should be resolved in a timely manner and provide for

an economic nature rather than to protect health.”

80. J Pemán Gavín, *Asistencia sanitaria pública y libre prestación de servicios ...*, cit., 128-29.

81. The distinction between hospitals and non-hospitals is more difficult in practice, since not all member states set out a single definition of what is meant by hospital service. Many States regard hospital care or treatment as not requiring admission, but certain structures with equipment are typically found in hospitals.

judicial review in case of rejection.

- Prior authorization may only be withheld upon request of treatments that do not fall within the list of benefits from the State of origin or are not considered usual in international medical science, and care cannot be provided in State of origin.
- In addition, refusal to pay can be a serious detriment to the Social Security system (such serious damage would not occur if they could receive the same care in the state of origin or if the cost was not significantly different).

Certainly the economic impact of medical tourism and cross-border healthcare is not especially relevant. The Commission estimates that around 1% of public healthcare budgets are spent on cross-border healthcare, which equates to around €10 billion for the Community as a whole. The share can be higher in some cases such as in border regions for smaller member States, and for rare diseases in areas that attract large numbers of tourists⁸² The largest number of patients from other EU Member States treated in a single member state under the E-112 form was 14,061, in 2000 and cost € 25,907,697.⁸³

For the Commission this relatively small scale of cross-border healthcare is not surprising, as people prefer to have healthcare as close to home as possible. The Commission surveys show that healthcare needs of the vast majority of patients throughout the EU are met through the healthcare provided by their domestic system. Although this framework is of great importance for the individuals concerned, the overall volume of cross-border healthcare will not have a major impact on health systems as a whole⁸⁴. Furthermore, the Commission believes that although patients are becoming more aware of healthcare possibilities in other member states, mobility is likely to remain limited. There may be some specific situations where mobility may be useful for both for patients and for systems as a whole, in providing care more quickly, efficiently and effectively. However, the overwhelming majority of care will continue to be provided within national systems⁸⁵.

82. See Commission Regulation 1408/7, 1971 J.O. (L 28) 8. Explanatory note from the Commission Services on the provisions of the proposed Directive on services in the Internal Market relating to the assumption of healthcare costs incurred in another Member State with a particular emphasis on the relationship with Regulation N° 1408/71, 8.

83. *Id.*

84. Commission Regulation, *supra* note 82, at 8 (Communication from the Commission of 2 July 2008, about a Community framework on the application of patients' rights in cross-border healthcare.).

85. See Commission Regulation, *supra* note 82 at 9 (Explanatory note from the Commission Services on

The phenomenon of medical tourism and the problems derived from cross-border healthcare constitutes a legal factor of significant importance and even possibly an economic factor. The economic impact does not have a great impact on the development of a common healthcare framework. In addition, this advance has not been instigated by the communities' institutions with a political base, such as the Council, Parliament or Commission, but rather through the judicial power of the European Union.

We can conclude that the European healthcare framework has advanced its progress through judicial means, which means that its creation has come about as a result of case law. The Court's resolutions dealt with the issues of cross-border healthcare and they were simultaneously creating a common policy of healthcare based on the law. Political, legislative and executive institutions have been forced to turn their heads to the challenge posed⁸⁶.

The Court of Justice's doctrine regarding the movement of patients is a case-by-case analysis, which responds to the peculiarities of each case (hospital or non-hospital, reimbursement systems in kind, etc.). However, there is no common doctrine which could apply to all Member States. The proclamation of the law ultimately has individualistic leanings where the interest of the community to which it belongs is not included, which is necessary to effectively evaluate the case. It does not resolve an issue with claims of generality, but rather specific cases of citizens who are not satisfied following reimbursement claims. The Court does not appreciate the consequences of the situation that the individual decisions can generate.

A key function of health systems is to establish priorities based on an assessment of what most benefits the community as a whole (public interest). This translates into planning decisions and funding the health system. Such a view necessarily disappears when the decision arises from the context of an individual's dispute.

On the other hand, the Court's view has not been respected either by

the provisions of the proposed Directive on services in the Internal Market relating to the assumption of healthcare costs incurred in another member state with a particular emphasis on the relationship with Regulation N° 1408/71, 9.).

86. See *Commission Proposal on Follow-up to the High-Level Reflection Process on Patient Mobility and Healthcare Developments in the European Union*, at 6, COM (2003) 301 final (Oct. 28, 2004). The European Economic and Social Committee has recognized the role that the Court has had in the development of the framework for health. Concerning the problem of the free movement of patients, COJ case law has made significant progress over time in paving the way for practical implementation of the right of free movement of patients and the sick based on the fundamental freedoms listed in the Community Treaties, and also overcoming the major differences between national healthcare and health insurance systems.

the Member States or by the European institutions themselves, which forces citizens to the courts to satisfy claims since there is no other way to resolve a reimbursement conflict. Most member states showed initial opposition to amending the internal regulation of the borders. Some member states argued that the particular case decided by the Court did not apply to their healthcare model⁸⁷.

In addition, most court decisions refer to situations that come about in Member States whose health systems are the reimbursement model according to public tariffs (*see*, France, Belgium, and Luxembourg). The state of origin does not have to reimburse all medical aid, but rather only the expenses incurred on the corresponding tariff (on occasion the reimbursement rate that is more beneficial to the person concerned will be applied whether incurred in the state of origin or the state in which aid has been delivered). On the contrary, since many systems, such as the Spanish system, which is based on the assumption of one hundred percent of the costs, reimbursement of expenses incurred by Spanish persons in another Member State can be very burdensome.

The decisions of the Court of Justice, are not being contested. National decisions regarding the decisions the court has issued have concentrated mainly on the approval of tariffs, which would allow the amount of reimbursement to be defined and the regulations around the area of the prior authorization. It seems that the majority of Member States are aware of the fact that when the *Watts* case was issued, it was already clear that the European Commission would bring forward a specific legislative proposal on patient mobility. Therefore, several of these countries seem to be awaiting the adoption of this Directive before taking further action.⁸⁸

Health tourism is a reality in many countries of the Union; however, the Union has not developed procedures for the reimbursement of expenses incurred under this provision,⁸⁹ nor have they carried out an active policy against this phenomenon. In the case of Spain, the doctrine

87. Rita Baeten, Bart Vanhercke, & Michael Coucheir, *The Europeanisation of National Health Care Systems: Creative Adaptation in the Shadow of Patient Mobility Case Law*, OSE PAPER SERIES, July 2010, at 24.

88. *Id.*

89. In the autonomous region of Valencia (Spain) it has been calculated, according to the data from 2005 it was only possible to recover 27,000,000 of the 80,000,000 euros that healthcare to foreigners cost. *See* J.L. Rodríguez-Vigil Rubio, *Integración o desmoronamiento. Crisis y alternativas del Sistema Nacional de Salud español*, Thomson-Civitas, Cizur Menor, 243-44 (2008). In this regard, the compensation is wholly virtual because, while health care spending of EU citizens living in Spain in 2006 reached the figure of 275,240,237 euros, conversely, expenditure incurred by the Spanish citizens residing outside one of the EU countries was 10,957,549 euros.

notes that the permissive nature has been motivated by the supposition that tourism is a key economic activity for the country and that the quality and security of the public healthcare system are important factors for its competitiveness.⁹⁰

Therefore, the problem has neither been addressed in a global manner by the political institutions of the EU, nor in the field of the Member States, especially by those most affected by the consequences, those employing the national health system.

Some authors have warned of the risks of the position of the Court of Justice and have pointed out that it is possible that the consolidation of the doctrine regarding medical tourism could force the European Union, the Member States, or both, to decide to reduce healthcare provision⁹¹.

As the European Economic and Social Committee (EESC) warned, although health systems fall under the remit of the Member States and leaves unchanged practices for reimbursing treatments provided. However, the provisions proposed will necessarily have an impact in the long term on health systems, which are based on solidarity and financial sustainability⁹². Particular attention should be paid to certain medical risks linked to increased patient mobility and poses a new scenario in which the EESC also recommends that the compulsory liability insurance system should be extended to include all healthcare professionals⁹³.

Likewise, mobility will require further standardization of the rights of patients. In this regard, we must remember that the legal rights of patients are of great importance in the field of professional liability, and that rights are translated into obligations for health workers and failures of those obligations must translate into a system of personal liability and economic reimbursement for the damages for the patients. Consequently, in the EESC's view, the text should not propose to make patient mobility common practice but should put forward a framework in which this right can be exercised, without neglecting the need for quality healthcare as

90. *Id.* at 238-39. See also, Magdalene Rosenmöller et al, *Meeting the needs of long-term residents in Spain*, in PATIENT MOBILITY IN THE EUROPEAN UNION: LEARNING FROM EXPERIENCE 59, 65 (2006).

91. The European Union and Health Services: The Impact of the Single European Market on Member States, *supra* note 36, at 374 ("Impacto de las políticas de la Unión Europea sobre los sistemas sanitarios."). See also, European Economic and Social Committee, *supra* note 4 (saying on July 16, 2003 in regard to healthcare provisions, "There is also a risk that social and healthcare guarantees will be eroded. This could lead to an exodus of professionals and patients to those Member States with the best organized healthcare systems.").

92. *Opinion of the Economic and Social Committee on the Proposal for a Directive of the European Parliament and of the Council on the Application of Patients' Rights in Cross-Border Healthcare*, at http://eescopinions.eesc.europa.eu/EESCOpinionDocument.aspx?identifier=ces\soc\soc322\ces1927-2008_ac.doc&language=EN.

93. *Id.* at 2.

close to the patient as possible. The mechanisms introduced should not be disproportionate to the scope of cross-border healthcare⁹⁴.

VII. THE POLITICAL RESPONSE TO THE COURT OF JUSTICE: THE CROSS-BORDER HEALTHCARE DIRECTIVE

The political institutions of the European Union have tried to respond to the doctrine regarding cross-border healthcare drawn up by the Court of Justice through a significant number of rulings. They recently approved and published Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 (“the Directive”) on the application of patients’ rights in cross-border healthcare⁹⁵.

The Directive states that Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with the Directive by October 25, 2013. The Member States shall inform the Commission of compliance at that time.

The Directive provides rules for facilitating the access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between Member States, in full respect of national competencies in organizing and delivering healthcare. Furthermore, the transposition of the Directive into national legislation and its application should not result in patients being encouraged to receive treatment outside their Member State of affiliation.

Similarly, the Directive admits, in part, that its *raison d’être* is found in the doctrine of the Court to just mentioned: The Directive is intended to achieve a more general, and also effective, application of principles developed by the Court of Justice on a case-by-case basis. Thus, it is intended to solve the main problem that the construction of a right to cross-border assistance presents when based solely on the individual cases presented, by attempting to provide such a provision with a legal framework that is clearer than what a mere collection of case law can provide, in agreement with the principal of legal certainty⁹⁶.

The Directive also does not limit the scope of health care in the strict sense, but also covers prescription drugs. Thus, the concept of cross-border healthcare includes not only healthcare costs but also the prescription, and dispensation and provision of medication products and medical devices).

94. *Id.* at 2.

95. Directive 2011/24/EU of 9 Mar. 2011, 2011 O.J. (L 88) 1.

96. *See id.* The Directive also fills the void that has resulted in the elimination of health services from Directive 2006/123/EC of the European Parliament and the Council of Dec. 12, 2006 regarding services on the market.

Thus, the patient can acquire medication not only in a State other than that of his membership, but in a Member State other than the State of the prescription's issue.

On the contrary, the Directive is not applicable for neither the long-term care provided by home care services in nursing homes or other assisted care, nor the access and allocation of organs for transplant, nor the rules of the Member States relating to the sale of medicines and health products online.

In terms of content, it is important to note that the Directive does not attempt to eliminate the requirement of prior authorization that Member States may require to repay the amount of assistance received by its citizens in a State other than the insured. Such authorization is maintained; the Directive shall not affect laws and regulations in Member States relating to the organization and financing of healthcare in situations not related to cross-border healthcare⁹⁷.

Moreover, according to the Directive, the Member State of affiliation may establish grounds to limit the reimbursement where this can be justified by having overriding reasons of general interest, as stated by the Court of Justice. Furthermore, as the Directive indicates, the concept of "overriding reasons of general interest relating to public health" continuously evolves in the court of justice. Some reasons thought to be "overriding reasons of general interest" are capable of justifying an obstacle to the freedom to provide services such as planning requirements relating to the aim of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid waste of financial, technical and human resources. Other cases have recognized this is not an obstacle. The Directive states that inflows of patients may create a demand exceeding the capacities existing in a Member State for a given treatment. In such exceptional cases, the Member State should retain the possibility to remedy the situation on the grounds of public health.

This would seem to suggest that the new system would be flexible enough to allow Member States to carry out, with certain degree of comfort, the reimbursement of cross-border healthcare, given that cross-border healthcare would be limited to healthcare which the insured citizen would have the right to in his own state of affiliation.

However, this affirmation is not correct following thorough reading

97. In particular, nothing in the Directive obliges a Member State to reimburse costs of healthcare provided by healthcare providers established on its own territory if those providers are not part of the social security system or public health system of that Member State.

of the Directive. It is established that, in light of the case law of the Court of Justice, making the assumption by the statutory social security system or national health system of costs of healthcare provided in another Member State subject to prior authorization is a restriction to the free movement of services. Therefore, as a general rule, the Member State of affiliation should not assume of the costs of healthcare provided in another Member State subject to prior authorization, where the costs of that care, if it had been provided in its territory, would have been borne by its statutory social security system or national health system.

On the other hand, from the content of the Directive it seems, although the factor of the prior authorization remains, each Member State will have to approve a clear and objective legal framework regarding said authorization, so that rejection of the authorization may no longer be based on mere subjective assessments or evaluations made by the State from which the reimbursement is claimed. The protocol for prior authorization and the motives that could elicit a negative response shall be limited to what is necessary and proportionate, may not constitute a means of arbitrary discrimination, and shall be made publicly available in advance (transparent mechanism).

This requires, in short, that Member States regulate various issues, such as the portfolio of services (basket of healthcare), charges (fees) of every act or medical treatment, or even the criteria quality and safety of the healthcare provided.

In reference to the “portfolio of services” (basket of healthcare), the Directive does not intend that the Member State be forced to extend them, but rather define what the portfolio is so that the citizens affiliated are able to know which healthcare provisions are covered by reimbursement and which are not. It does state, however, that if the list of benefits does not specify precisely the treatment method applied but defines types of treatment, the Member State of affiliation should not refuse prior authorization or reimbursement on the grounds that the treatment method is not available in its territory, but should assess if the cross-border treatment sought or received corresponds to benefits provided for in its legislation.

Similarly, if the State of affiliation is only required to reimburse the amount that it would have taken on if the healthcare had been provided in its own territory, in order to deny part of the amount a previously established list of tariffs regarding each treatment must exist.

On the other hand, the need to define quality and security criterion on the part of the Member State derives from the fact that the Directive

foresees the state of affiliation could deny reimbursement when the assistance received is done so in a manner which does not fulfill its defined levels of quality and security⁹⁸. This question is complex, as many Member States have not approved a portfolio of services.

Furthermore, prior authorization can only be required in three cases: when it involves overnight hospital accommodation of the patient in question; requires use of highly specialized and cost-intensive medical infrastructure or medical equipment; or in serious and specific concerns relating to the quality or safety of the care. In these three cases patients will have to request prior authorization from the state which would be responsible for reimbursement.

On other issues, the Directive stresses the importance of the shared medical records for the cross-border healthcare system to function. To ensure continuity in cross-border healthcare the relevant personal data will have to be transferred. It must be possible for personal data to circulate. For this reason the Directive contains a specific article regarding eHealth: article 14.

Finally, the Directive makes reference to an important issue surrounding the idea of a common healthcare space, that of the reference networks. It establishes that the Commission shall support Member States in the development of European reference networks between healthcare providers and centers of expertise in the Member States, in particular in the area of rare diseases⁹⁹.

European reference networks shall have at least three of the following objectives: to help realize the potential of European cooperation regarding highly specialize healthcare for patients and for healthcare systems by exploiting innovations in medical science and health technologies; to contribute to the pooling of knowledge regarding sickness prevention; to facilitate improvements in diagnosis and the delivery of high-quality, accessible and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare; to maximize the cost-effective use of resources by concentrating them where appropriate; to reinforce research, epidemiological surveillance like registries and provide training for health professionals; to help Member States with an insufficient number of

98. Art. 8.2(c). The Directive refers to this matter in the following eloquent terms: “[B]e provided by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union”.

99. Art. 12.1.

patients with a particular medical condition or lacking technology or expertise to provide highly specialized services of high quality¹⁰⁰.

In short, the Directive has tried to regulate what constitutes a consolidated doctrine from the Court of Justice on cross-border healthcare and patient mobility in Europe. It is commendable, especially if we consider the position of the Commission itself in all cases brought to the Court of Justice regarding reimbursement claims from citizens against their states of affiliation¹⁰¹.

Therefore the position of the Court of Justice has enforced what a common healthcare area refers to in a specific sense regarding cross-border healthcare.

Moreover, this attempt to regulate the doctrine of the Court must be positively evaluated in order to prevent distortions produced by a legal system built upon case law. Under the Directive we find a general framework, which establishes both the rights of European citizens as well as the powers the Member States will have to correct distortions in the future.

However, not all problems are solved by the Directive, as it cannot expect to regulate a situation so rich, complex, and case-by-case based as cross-border healthcare in one fell swoop. Several legal concepts and provisions are not fully defined. Not until the Member States implement and apply the Directive will it be clear which of the criteria used by the Court lack in definition or clarity.

Nevertheless, it is also true, as various authors have indicated, that regularization provoked the fact that Europe now lives with parallel legal systems, created in the 1970s with the objective of coordinating social security systems (See Ruling CEE no. 1408/71 and Ruling Ce no. 883/2004) and that their content regarding healthcare is applicable to cross-border healthcare, and the new regime established by the Directive. In short, a double cross-border healthcare system has been created, establishing a procedure for reimbursement of medical expenses incurred outside the State of insurance (based directly on the EC Treaty), and while maintaining the existing procedure of coordination through Social

100. Art. 12.2.

101. Traditionally counsel for the Commission have supported the argument of the Member States against the legal provision for cross-border healthcare and as such have normally rejected reimbursements. This was more in order to prevent the widespread phenomenon than because there were actually specific reasons based in the case of the concerned citizen. It is true that the phenomenon of cross-border healthcare is not a factor that, quantitatively, supposes a particular problem for the Member States. However, many of them, especially those who have established a model of national health system (such as Spain or the UK) are concerned about the future developments of this phenomenon.

Security. This has added to the previous administrative complexity and lack of clarity of rights and cover¹⁰².

However, the Directive does not define what the role of the private sector should be in this model. It is true that the Directive does not limit its regulation to public health care providers, but to any person or entity legally providing healthcare in the territory of a Member State (art. 3 g), covering healthcare, related services provided by healthcare professionals to patients to assess, maintain or restore their health, including the prescription, dispensing and supply of pharmaceuticals and medical devices (art. 3). But it goes further, as would the alternative of establishing a system whereby, for example, private insurance for citizens would have some impact on the public system through tax deductions¹⁰³.

The Commission itself indicates that within the new strategies being developed to guarantee the sustainability of the healthcare system there is a clear role for the private sector to play¹⁰⁴.

VIII. LESSONS FOR THE FUTURE HEALTHCARE SYSTEM IN THE UNITED STATES

Various lessons can be drawn from the European experience and applied to the future North American national health system which seems to have come about, following a history of Medicare and Medicaid, from the law passed on the push of the Obama Presidency (*Patient Protection and Affordable Care Act*) and beyond to the future healthcare area in North America (USA, Canada and Mexico. However, we must not forget that there are significant difference between the US and European which mean that the experience is not fully transferable to the American scenario.

It is true that the origin of the attempt to establish a common health system in both Europe and the United States has been supported mainly by the judiciary. If in Europe the driving force of common space, at least in the field of cross-border healthcare, has been the Court of Justice, in the United States the role played by the Supreme Court has also been crucial. The Supreme Court doctrine that began in the first half of the twentieth century, especially from the case *Massachusetts*

102. W Palm & IA Glinos, *supra* note 73.

103. Such an alternative has already been mentioned in the Opinion of the European Economic and Social Committee on 'Healthcare', 16 July 2003: "Concerning lower priority forms of care which are not matters for public health policy, there has been a rise in supplementary insurance schemes".

104. "It may be necessary to clarify the role of duplicate and complementary private health insurance vis-a-vis publicly funded provision, to avoid raising inefficiencies in the public sector and to ensure cost-effective use of services. See European Commission, *Joint Report on Health Systems*, 74 OCCASIONAL PAPERS 13, (2010).

v. *Mellon*, 1923¹⁰⁵, which became generalized from 1953 with the Warren Court, which allowed the Congress to advance its policy of awarding grants to states-in-aid, conditioned on compliance with a set of goals or guidelines which facilitated the promotion of uniform policies regarding social welfare and, in particular health. It also has special significance if we consider the fact that such policies that ended up being defined by the Congress referred to competition matters, not of the Federation, but of States.

This doctrine seems to support the constitutionality of the *Patient Protection and Affordable Care Act* in its attempt to limit the power of the individual States over regulation of the health insurance market. Thus, although it is questionable whether the U.S. Constitution allows for federal regulation on an area such as healthcare, it does not provide for any specific power for the Federation, it seems quite evident that overall unconstitutionality of the law could not be based on the invasion of state powers.¹⁰⁶

We can therefore affirm that the remote source of a common healthcare system both in Europe and in the United States should be located in the judicial power and not in that of the legislative or the executive.

However, as we have previously noted, there are other notable differences between one system and another.

In the first place, the aspiration to construct a common healthcare area is something that, in Europe, has been caused independently of the political and economic aims of political institutions but rather by the phenomenon of cross-border healthcare and medical tourism. Opening the borders for free movement of citizens in a single area also opened up the situation which gave rise to cross-border healthcare. Member States have had to plan and budget for health spending paying attention for factors as unpredictable and complex as the movement of people wanting to receive healthcare outside of their state of origin and this ended up requiring a common policy transcending the Member States borders.

Therefore, cross-border healthcare has turned into a factor which has caused the necessary formulation of a common healthcare area, despite the fact that there are not provisions for it in the founding Treaties.

105. Sáenz Royo highlights the importance of *Chas. C. Steward Machine Co. V. Davis* of 1937 and *Carmichael v. Southern Coal & Coke Co.* of 1937. See Eva Sáenz Royo, *La reforma sanitaria de Obama en el marco del federalismo norteamericano*, 11 REVISTA GENERAL DE DERECHO CONSTITUCIONAL 7 (2011).

106. Eva Sáenz Royo, *La reforma sanitaria de Obama: La clave puede estar en la e-Salud*, 19.

On the contrary, reform of the US healthcare system is an old aspiration, especially for the Democratic Party, which responds to the ethical and social dilemmas posed by that part of the population, which in the pre-2010 system, were not covered by the system nor could be so. This lack of coverage is even more unjustifiable when health spending in the U.S. is much higher than in European countries with more developed health systems under the principles of free and universal healthcare.

Possible problems arising from cross-border healthcare are not what have paved the way for reform. In addition, this issue does not seem to have posed special problems because the American system is more homogeneous.

We should bear in mind that the US system is not based on these principles of universality and solidarity on which European systems are based. It is a system based, with the exception of Medicare and Medicaid, on an insurance model from work contracts. It can be said the the North American model is, in principle, a more restrictive and more homogeneous system, giving rise to the idea that cross-border healthcare does not have to assume an unbalance between states. On contrary, in Europe, we recall that the two models that are primarily used, that of the Bismark model (insurance) or the Beveridge model (national health system). There are therefore European States which offer more services or healthcare which does not involve a payment than others, which creates an unbalance. Citizens travelling with intention of obtaining medical treatment can receive more and better services without running the risk of having to make monetary contribution.

The fact that health is one of the greatest examples of the centralization of American Federalism should also be taken in to account when addressing this question of cross-border healthcare. Starting with grants-in-aid approved many years ago in the healthcare field¹⁰⁷ and continuing with the Supreme Court interpretation of the commerce clause in terms of the health sector, it may be said that the commitment to a homogeneous healthcare model has greater potential in the US than in Europe, and that it is strongly influenced by the cross-border healthcare factor.

It is true that a common language facilitates the cross-border healthcare factor. In effect, medical tourism and cross-border healthcare are not very widespread in the European Union due mainly to one factor: the

107. In 1888 the U.S. Congress approved an annual grant of \$ 25,000 for the care of veterans, thus determining public policy in this area of States. See *id.* at 4-5.

language barrier. Citizens know they can move freely around the United States and under its regulation, go where they can receive better medical care at a lower cost. However, many European citizens forego the possibility on the basis of a different language, especially when it comes to health. By contrast, in the United States, no such barrier exists so the phenomenon may well be on the rise in coming years. However, despite the linguistic element having an effect, the homogeneity of the model seems to redress imbalances that occur in Europe.

There may be some significance for the phenomenon of cross-border assistance to the United States in the field of healthcare professional liability. Increased cross-border aid may lead to new risks, new opportunities for medical error,¹⁰⁸ and consequently, new cases of medical liability. This is a matter which has not overly concerned the community's institutions; perhaps because there does not seem to be an especially relevant relationship between health spending increases and the increase in medical liability cases. However, in the United States this increase in liability arising from increased cross-border assistance itself can have major consequences, given past experience, especially after the so-called malpractice crisis.

Some authors believe that healthcare reform must necessarily include a reform of the medical liability system for three main reasons: a) "*Substantial malpractice liability is a driver of the escalation of health care costs*", b) "*to garner physician support for an omnibus bill Doubt That will not create a more stringent environment for Financial Health Care Providers*", c) "*to Attract support from congressional Republicans for a Health Care Reform package*"¹⁰⁹.

That question itself is addressed by the Patient Protection and Affordable Care Act, whose Section 10607 regulates the "State demonstration programs to evaluate alternatives to current medical tort litigation, they can grant *grants* to States for their development, on the dual strategy of allowing resolution of disputes over injuries allegedly caused by healthcare providers or health care organizations, makes the medical liability system more reliable by increasing the availability of prompt and fair resolution of disputes and reduce medical errors by encouraging the collection and analysis of patient safety data.

Furthermore, European health systems, being formulated on the

108. Medical errors may occur because there is not the same sharing of health data among professionals at the same health center, or even the same area as between professionals that are at miles away.

109. M. M. Mello et al., *The role of Medical Liability Reform in Federal Health Care Reform*, 361 NEW ENGLAND J. MED. 1, 1-2 (2009).

insurance model or the model of the national system, highlight the important leading role assumed by the Public Administration. Public authorities are the main players in the European model, although at a State level, even when they provide for extensive holdings of private companies (either via insurance or support through concessions management of hospitals or similar). Therefore, in the European model the task of coordinating the system is simpler; it is more complex in a competitive system led by private companies. For example, expenditure control is more feasible when the system is controlled by a major player and this is the Public Administration. While health spending has been increasing in the United States in recent decades, in Europe, by contrast, the increase in spending has slowed from the 90s as a result from public policy control¹¹⁰.

Therefore, although the U.S. model is apparently more homogeneous than Europe (private model based on collaboration of health care insurance companies), the main managers of the system, private insurance companies, are more heterogeneous than in Europe, which does not affect cross-boarder healthcare, it can affect the system in terms of expenditure control.

As such, the US model would have to develop, in the light of the European experience, a greater role for the United States, as has been the case, especially in the second half of the twentieth century through such elements as the grants-in-aid and total or partial pre-emption. Such strengthening of the federal role would be required in order not to homogenize the model itself, but to standardize the guidelines to be followed by the main managers of the system, for example, health insurance companies. Any attempt to strengthen the power of the US States on this issue will result in reduced control over health spending due to a lack of policies and guidelines regarding the same.

If the system ends up being fifty different models for the States (either at the hands of the states, as seems to have occurred in Virginia, Idaho, Utah, Arizona, Oklahoma and Missouri, or at the hands of the Supreme Court following legal disputes from States opposed to reform - Florida and Virginia-), cost control, and therefore the sustainability of the system, might seem impossible. Moreover, in this context, cross-border healthcare does pose a real problem, as in Europe.

Last, Member States and Community institutions are fully aware that the common area health inexorably requires the development of new

110. North American authors have highlighted this. See Robert Crane et al, *Health care reform: What the United States can learn from the experience of other developed nations*, 45:2 HEALTH SERVICES RESEARCH 600 (2010).

technologies in health and, most notably, the development and implementation of shared digital medical records. It is arguable that the achievement of a common coordinated area minimally requires the implementation of a digital medical records system or at the very least some basic health data sharing. This fact is relevant as an example for the United States, since their health care system shows a significant deficit in this area¹¹¹.

Thus, one of the main policies that would be developed under the Patient Protection and Affordable Care Act is precisely to promote health and technology, especially shared medical records. Without it, the reform will be doomed to failure¹¹².

In short, it has been suggested that "the European model of economic integration which addresses the social needs of a mobile population could well serve as a model for North America," because the phenomenon of health tourism and the demands of cross-border healthcare is required "to develop mechanisms by which individuals can enjoy the health coverage benefit of their state of origin while working or visiting in other parts of the EU." Such access to and coordination of health coverage does not exist to the same extent in North America¹¹³.

IX. CONCLUSIONS

We can neither say that there currently exists a common framework for healthcare in the European Union nor that its development will come about in the near future. It is further hampered by the lack of a regulatory framework to enable the European Union to launch it, under the founding treaties. While the Treaty of Lisbon has represented an increase in EU powers over healthcare, it does not assert that this matter has ceased to be a Member State power. What is true, however, is that the work of coordination and support the European Union can take on, especially under the principal of subsidiarity, strengthens the future of common policies in the field of health.

111. This is highlighted by various American authors: "The US lags well behind other nations in the use of electronic medical records: 17 percent of US doctors compared with 80 percent in the top three countries." See Jack A. Ginsburg et al, *Achieving a high-performance health care system with universal access: What the United States can learn from other countries*, 148 ANN. INTERNAL MED. 62 (2008).

112. It is true, however, that the Patient Protection and Affordable Care Act includes various provisions regarding *data collection*, aiming to promote "the use of the systems that provide data to improve and coordinate patient care" (Section 3015) and also considers that many of the attempted reforms hinge the development of *electronic health record*. Patient Protection and Affordable Care Act, Pub. L. No. 111 – 148 § 3015.

113. Eleonor D. Kinney, *Health care financing and delivery in the United States, Mexico, and Canada: establishing intentional principles for sound integration*, 26 WIS. INT'L L. J. 943 (2009).

In addition, community institutions themselves are now well aware that health matters cannot remain outside the common economic space towards which the EU advances, and cannot forget that to involve European citizens in this challenge they must perceive that the construction of the future European Union will lead to greater health protection.

Therefore, in the absence of a specific regulatory framework, the community institutions have developed various projects and programs that come into the scope of health care. Among them, we can highlight the clinical data-sharing project, which has been shown to be indispensable for the full development of a common area of health.

Out of these timid political attempts to move towards the common area of health, it has been the Court which has taken the reins of the challenge and, for the past few decades, has been constructing a doctrine that has opened up the possibility of cross-border healthcare in a common European space. Moreover, the doctrine of the Court has already been collected under a legal regime approved in early 2011 by the European Parliament and Council.

There is still much left to do and, above all, it remains to be determined what kind of common healthcare framework it is to be, whether limited to an area with the assurance of cross-border healthcare cost reimbursement or a real space in which a single catalogue of common benefit for citizens health is established, according to a single European quality standards and safety. Additionally, this more ambitious common framework model, would lend particular importance to the development of European Reference Centres for certain pathologies which gather far more experience than of the merely national.

Finally, as regards the future model of the United States, the European experience may offer some lessons, not to mention some important differences between both models. Specifically, the main lesson is that the U.S. model would seek to strengthen the federation as a way to standardize a model in which diversity will come from the role assigned to different private providers of health services. If the problem in Europe, from the point of view of the homogeneity of the resulting model and cost control is the existence of different national health systems, the problem in America is the existence of different health system managers. The private insurance companies will have a very active and important participation. Strengthening the Federation seems likely to allow homogenization of the relevant guidelines and, therefore, expenditure control.

Also, another item which merits attention is the development of health technologies in both the European model as well as the U.S. model. This would include electronic medical records as a key instrument for the proper function and sustainability of the system.

